IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: DIGITEK PRODUCT LIABILITY LITIGATION **MDL NO. 1968**

THIS DOCUMENT RELATES TO ALL CASES

MOTION IN LIMINE TO EXCLUDE UNRELIABLE HEARSAY

To support their opinions that defective Digitek® was released to market, two of Plaintiffs' experts refer to a post-recall e-mail message sent on April 30, 2008 from a nursing home staff member to a Mylan employee about a supposedly "double thickness" tablet. (*See* Exhibit 1 attached to this Motion). This document is (1) scientifically unreliable and does not pass muster under *Daubert*; and (2) classic hearsay, traditionally considered unreliable, and excludable under Fed. R. Evid. 802. The document should be excluded from evidence.

1. The April 30, 2008 E-mail Is Unreliable

According to the e-mail, someone who was apparently a nursing home employee reported finding what the document describes as "one double thickness tablet" in a "card." (Exhibit 1). This document is scientifically unreliable in many ways:

- Thickness of a tablet only millimeters in size is a measurement. It is not something that can be "eyeballed."
- The supposed "eyeball" observation was made while the tablet was within its packaging, a foil and plastic container called a blister pack, which would partially obscure the view and make accurate measurement impossible.
- The tablet was never removed from the blister pack and was never measured.
- The tablet was never returned to Actavis or Mylan for analysis.

- Nobody knows who actually made the observation.
- Nobody knows the observer's qualifications to "eyeball" such a key analysis of this pharmaceutical product.
- Nothing in the e-mail confirms the tablet was Digitek® manufactured by Actavis, as opposed to one of the other generic digoxin tablets that were on the market in April of 2008.
- If the tablet was distributed by UDL, it could not have been double-thick because UDL packaging limitations would not allow a tablet that is twice its intended size to be packaged.

UDL un-packages the product it purchases and then re-packages it into single-unit dose packages, called blister packs. (*See* Deposition of Liana Radtke at 51-52, attached to Defendants' General Background Statement as Exhibit 44). UDL custom designs all of its blister packs to the precise size dimensions of each separate product so that "[UDL] can't get two pills in [a blister pack][.]" (Radtke Dep. at 52:6-7). The blister pack is designed and made to hold tablets that are no more than 10% over their size specifications – if a tablet of double its intended thickness was introduced into the packaging process, the equipment would jam and actually shutdown. (*See* UDL Internal Investigation, attached to Defendants' General Background Statement as Exhibit 43; Radtke Dep. at 140:14-141:10). Also, it is undisputed that UDL never found any Digitek tablets outside the FDA-approved specifications. (*Id.*; Radtke Dep. at 134:1-135:6; 144:12-18). So, if the "card" was from UDL, the observation cannot be accurate.

Even Plaintiffs' experts concede the unreliable nature of this e-mail. For example, Dr. Russell Somma agreed it would be "impossible to accurately measure" a tablet enclosed within a blister pack. (See Deposition of Russell Somma, Ph.D, at 51:4-7, attached to Defendants' General Background Statement as Exhibit 15). If Dr. Somma was the consultant investigating this situation he would open the blister pack and weigh and measure the tablet. A report like this, without knowing the reporter, is not reliable. (*See id.* at 51:16-53:16).

Dr. David Bliesner admits he is not an expert in blister packs, does not know what UDL blister packs look like, and does not know the blister pack size specifications. (*See* Deposition of David Bliesner, Ph.D., at 59:23-60:13, 425:22-427:22, attached to Background Statement as Exhibit 14). He has never tried to eyeball a tablet in a blister pack. (*Id.* at 65:9-25). If he had to know the size, he would measure it. (*Id.* at 65:21-25). Dr. Bliesner did nothing to independently verify the accuracy of this e-mail, (s*ee id.* at 427:14-22), does not know the qualifications or reliability of the observer (*id.* at 63:1-5), and knows the tablet was neither returned to Defendants nor measured (*id.* at 59:1-11, 61:4-9). He concedes, therefore, it is only "possible" there was a double-thick tablet in the blister pack (*id.* at 434:10-16), and that he cannot come to a firm conclusion about it (*id.* at 437:22-438:2).

The bottom line is that this e-mail does not contain facts upon which any expert could reasonably rely as proof of manufacturing defect. It is not scientific, not corroborated, not verified or peer reviewed, and comes from an observer of unknown skill or experience who cannot be cross-examined. And not least, the phenomenon that it reports – a double-thick tablet in an unbroken blister pack – is not possible given the undisputed size specifications and restrictions for UDL's blister packs, if it indeed came from UDL at all. This is exactly the sort of unreliable evidence that courts should prevent from reaching a jury under *Daubert*, its progeny, and basic fairness. It is not direct evidence of defect, and it cannot form the platform for an inference of defect. Rather, it is wild speculation in the wake of publicity and lawyer advertising about a recall.

2. <u>The April 30, 2008 E-mail Is Hearsay and No Exception Applies</u>

The Federal Rules of Evidence provide a second ground for excluding the e-mail and any reference to the e-mail. The nursing home from which it originated is not a party to any Digitek®

case and there is no MDL plaintiff from Massachusetts. Also, fact discovery is closed and none of the witnesses from Massachusetts were ever deposed. Accordingly, Plaintiffs cannot possibly offer this document for anything other than the truth of the matter asserted in the e-mail – that a double thick tablet existed outside of Actavis's plant in 2008.

This document meets every classic test for hearsay under Fed. R. Evid. 801. Indeed, insofar as no one can confirm that the author of the e-mail was in fact the person who discovered the tablet, it may well be that this e-mail is "hearsay within hearsay" under Fed. R. Evid. 805. The document qualifies for no exception under Fed. R. Evid. 803 or 804. Under the Rules, therefore, it is "not admissible." *See* Fed. R. Evid. 802.

CONCLUSION

Plaintiffs' burden in a products liability suit is straightforward: they must prove that each plaintiff received, ingested, and was harmed by defective Digitek®. They lack any direct evidence and should not be permitted to use scientifically unreliable hearsay to fill in their lack of proof. This Court should preclude reference to this e-mail and bar any Plaintiffs' expert who seeks to offer a defect or causation opinion on the basis of this e-mail.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on August 3, 2011, a copy of the foregoing **DEFENDANTS' MOTION IN LIMINE TO EXCLUDE UNRELIABLE HEARSAY** was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

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